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Vaccine Storage and Handling

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Immunization Unit

Storage & Handling Topics

- Storage Units
- Water Bottle Requirement
- Vaccine Storage
- Temperature Recording Requirements
- Data Loggers
 - Requirements
 - Placement
 - Certificate of Calibration



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Storage & Handling Topics (cont'd)

- Storage Unit Power Supply
- Temperature Excursions
- Room Temperature Thermometers
- Vaccine Transport in an Emergency
 - Supplies for Transport
 - Vaccine Packing for Transport
- Managing the Cold Chain



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Storage Units

CDC Approved Storage Units

- Pharmaceutical grade (purpose-built)
- Commercial grade/household stand alone
- Combination (Refrigerator/Freezer)
 - Only use the refrigerator
 - Obtain a stand-alone freezer



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Storage Units

NO DORMITORY STYLE UNITS

Single exterior door with an interior freezer compartment



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Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

Storage Units

- Large enough to hold the year's largest inventory without crowding
- NO food or drinks stored with vaccine



Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>



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Water Bottle Requirement

- Sufficient number of water bottles
- Labeled “DO NOT DRINK”
- Placement:
 - Unit door
 - Top shelf
 - Floor
 - Vegetable/fruit bins
 - Near the vent
 - Along the walls



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Vaccine Storage

- Central area of the unit
- Do not store in:
 - Vegetable bins
 - Meat drawers
 - The door
 - The floor

Vaccines must be stored and/or stacked to allow cold air to circulate freely.



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Vaccine Storage

- 2-3 inches between vaccine and the walls
- Store each type of vaccine or diluent in a separate container
- First in, first out
- When possible, store diluent with the corresponding refrigerated vaccine
- Labels shelves and containers to clearly identify vaccine and diluent



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Vaccine Storage

- Store vaccines with similar packaging or names (pediatric and adult) on different shelves
- Clearly label “pediatric” or “adult”
- Keep vaccines in original packaging with lids closed
- Do not pack a unit too tightly
 - restrict air circulation
 - impact vaccine temperature
- Separate private vaccine from TVFC/ASN vaccine



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Temperature Requirements

- Refrigerator temperature range
36°F and 46°F (2°C and 8°C)
- Freezer temperature range
-58°F and +5°F (-50°C and -15°C)
- New or repaired storage unit:
 - 10 days of temperature readings/recordings
 - 10 days of minimum/maximum temperatures readings/recordings



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Temperature Recording Requirements

- Temperature logging is mandatory (even if data logger is used)
- Temperature Recording Form (EC-105)
 - Must be on or near all units that store TVFC vaccines
 - Maintain for 5 years
- Check and document temperatures twice daily of all units
- Check and document min/max once daily



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Data Logger Requirement

Effective January 1, 2018

Data loggers are required as the primary and back up thermometers



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Digital data loggers

Data logger Requirements (cont'd)

- Buffered material
 - liquid (ex glycol, ethanol, glycerin)
 - loose media (ex sand, glass beads)
 - solid block (ex Teflon®, aluminum)
- Centrally located probe
- Current certificate of calibration
- One back-up data logger
 - with a current certificate of calibration
 - stored outside of unit



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Data logger Requirements (cont'd)

Data logger required capabilities:

- Alarm for out-of-range temperatures
- Display current temperature, as well as min/max temperatures
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full)
- User-programmable logging interval (or reading rate)
- Detachable probe



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Data Logger Probe Placement

- The probe must be placed as close to the vaccine as possible.
 - centrally located,
 - main body,
 - away from walls, ceilings, cooling vents, doors, floor, and back of the unit
- The probe must not be
 - suspended from wire shelves
 - suspended from the ceiling of the unit



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Data Logger Certificate of Calibration

- Certificate of calibration
 - post on/near the unit
 - must contain:
 - model number
 - serial number
 - date of calibration
 - measurement results



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Certificate Information:

Certificate Number: C-13-04-16-019

Calibration Technician: S. Perez

Calibration Date: 2013

Next Calibration Due: 2014

Inc. of
Standards and Test

RHTemp200

The Temperature
certificate.

Published D

Accuracy:

Range:

Resolution:

Channel 1 - All

Point Sta

Actual T

1 25

Initial Con

Gain: 1

Offset: 0

Calibration And Service:

For information regarding this calibration,
shipped directly to MedgeTech, Inc. will reg.

Issued By:

Date:

2013-04-26

Approved By:

Date:

2013-04-26

Maintaining Calibration:

This product is manufactured from the highest quality components. The unit has been designed to remain within its specifications during normal use. However, the length of its tolerance service can be affected by low battery voltage, age, temperature, humidity, shock, and other environmental influences. For those users with critical performance or validation requirements, MedgeTech, Inc. recommends that the unit be serviced and calibrated at regular periodic intervals.

Certificate Number: C-13-04-16-019

Date Created: 2013-04-26

Date Printed: 2013-04-26

Certificate Page: Page 1

Company
Contact
Information

Number: P05758

Device Error

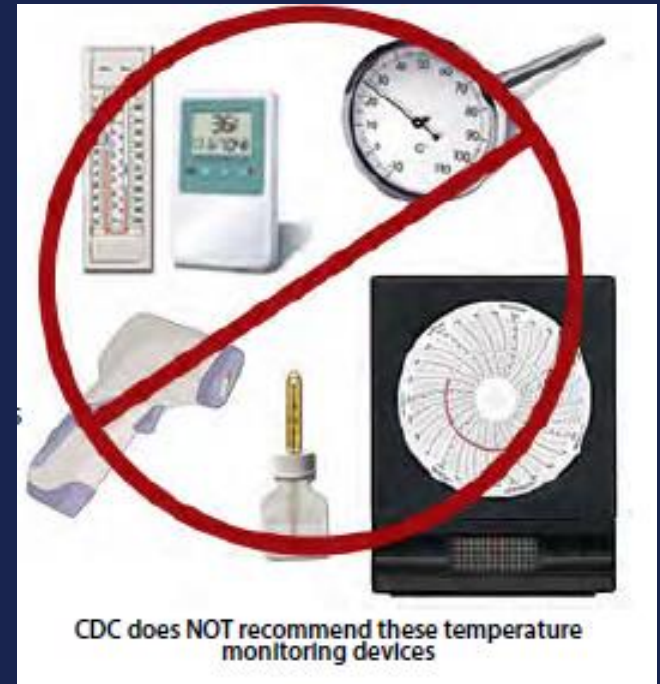
= Device Standard

0

Data Logger Requirements (cont'd)

Not allowed

- fluid-filled, bio-safe liquid temperature monitoring devices
- bi-metal stem thermometer
- food thermometer
- household mercury thermometer
- chart recorders
- infrared temperature monitoring devices



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Storage Unit Power Supply

- Protect unit's power supply by
 - plug directly into wall outlet
 - install plug guard
 - install DO NOT UNPLUG sign
 - install DO NOT DISCONNECT label



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Storage Unit Power Supply

- Do not use multi-outlet power strips
- Do not use outlets with built in circuit switchers (GFCI)
- Do not use outlets that are activated by a wall switch



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Temperature Excursions

Temperature excursions

- place vaccines in a vaccine quarantine bag and label “DO NOT USE”
- store vaccines under appropriate conditions
- contact vaccine manufacturer to obtain viability information
- contact responsible entity (DSHS HSR or LHD)
- complete the vaccine storage troubleshooting record (page 3 of EC-105)



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Room Temperature Thermometers

A thermometer to record room temperature is necessary when an excursion occurs in a vaccine storage unit.



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Emergency Vaccine Transport

Emergency transport situations

- Equipment failure
 - Power outages
 - Severe weather conditions
 - Natural disasters
-
- ✓ Do not leave vaccine in a non-functioning unit
 - ✓ Keep unit doors closed during a power outage
 - ✓ Transporting frozen vaccine requires special care



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Emergency Vaccine Transport

Be prepared

- completed Vaccine Management Plan
- back-up data logger
- flashlight with spare batteries
- vaccine transport materials
- after hours access to building



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Emergency Vaccine Transport (cont'd)

Vaccine Transport Containers and Materials

- portable vaccine fridge/freezer
- hard-sided (or Styrofoam) insulated cooler
- frozen water bottles
- insulating material (bubble wrap and corrugated cardboard cut to cooler size, two layers each per container)
- data logger



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Emergency Vaccine Transport (cont'd)

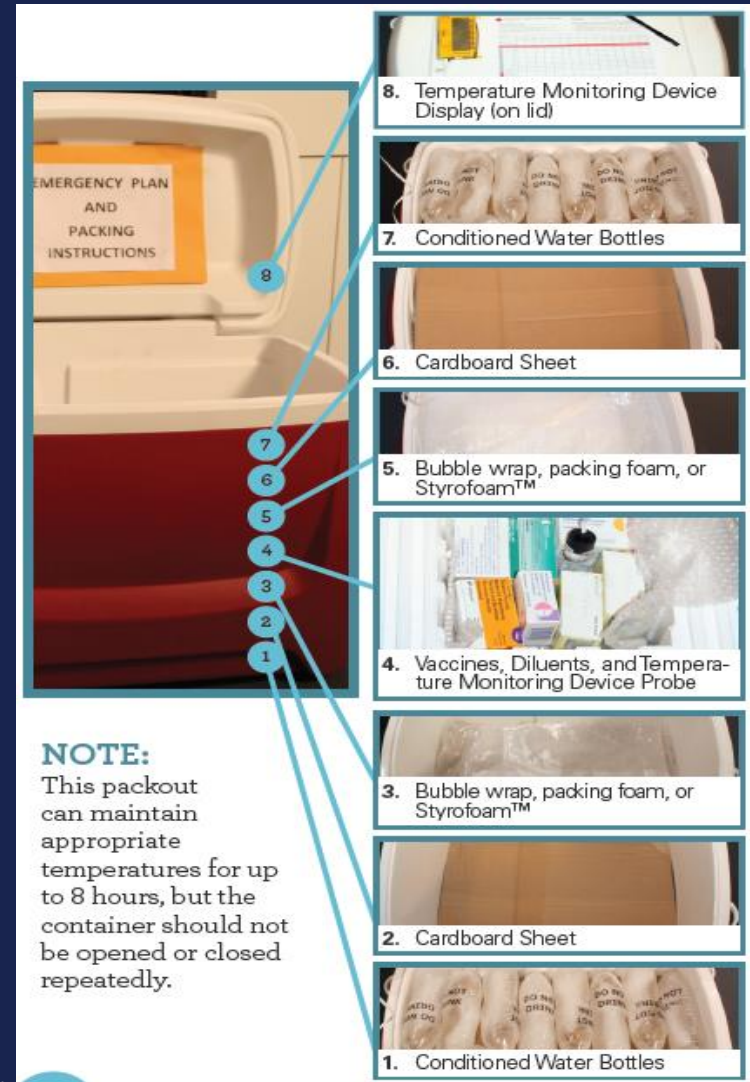
Packing vaccines in an emergency

- conditioned frozen water bottles
- corrugated cardboard
- bubble wrap
- vaccines
- data logger probe



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Emergency Vaccine Transport

Cold Chain Documentation (EC-105)

- Date and time transfer began
- Temperature of unit when vaccine removed
- Temperature of transport container when vaccines placed inside
- Temperature(s) recorded during transport
- Date and time transport was completed
- Temperature of unit at receiving facility



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Managing the Cold Chain

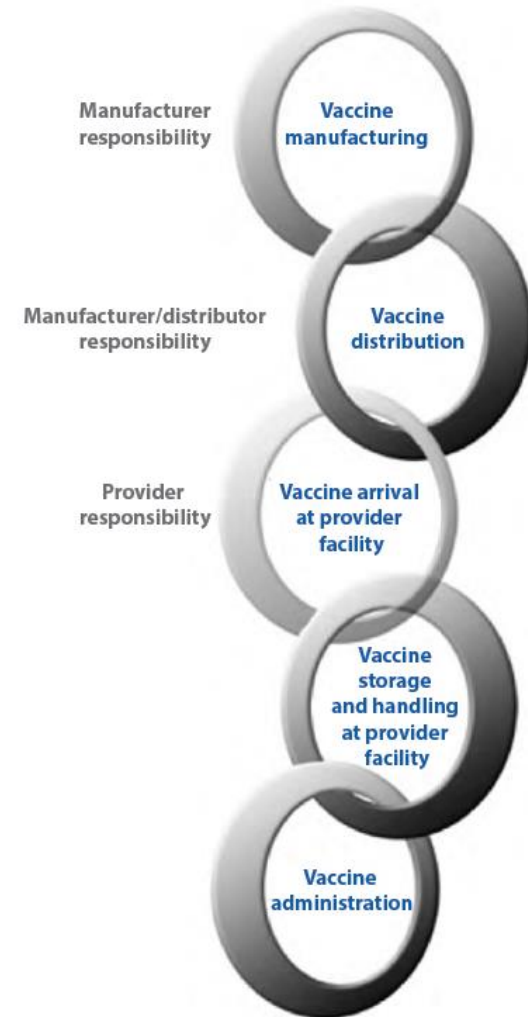
- exposure to heat, cold, or light can result in loss of vaccine potency
- potency cannot be restored
- continued exposure to improper conditions reduces potency further
- improper handling results in loss of potency



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Cold chain flow chart



Managing the Cold Chain

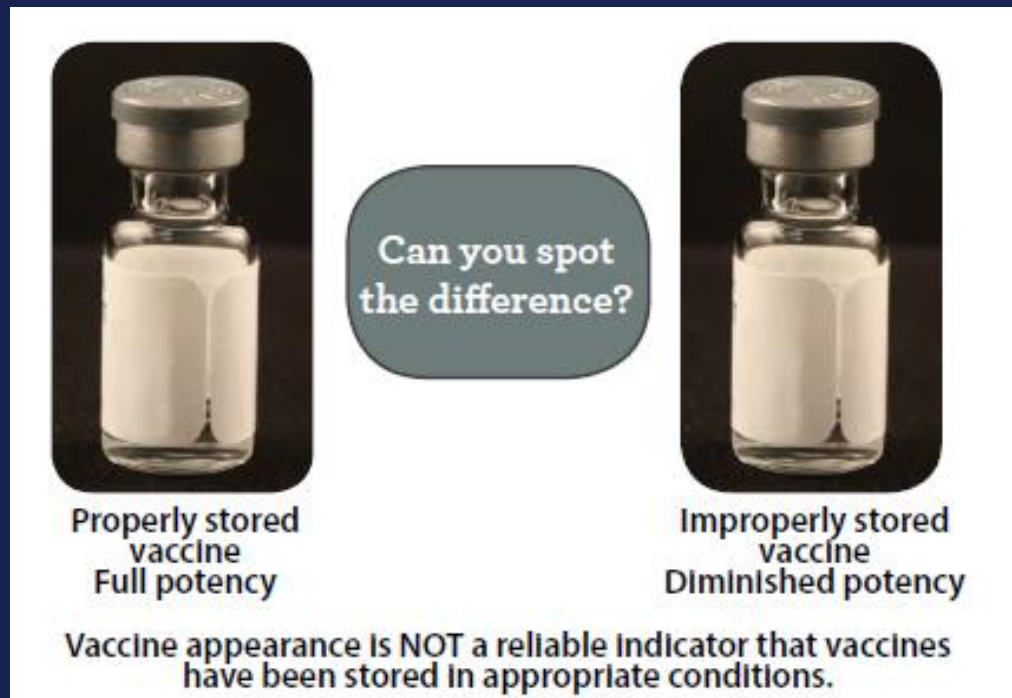
Compromised cold chain:

- no physical indication of compromise
- not effective in protecting your patients
- increase in disease cases



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Managing the Cold Chain

Four elements of effective cold chain:

- well-trained staff
- reliable storage units
- valid temperature monitoring equipment
- accurate vaccine inventory management

All clinic staff should be trained on proper storage and handling of vaccines



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Questions



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Thank You!

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